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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/921,406

08/02/2001

Zohar Yakhini

10010313-1
(2003309-0012)

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22878

7590

12/27/2005

EXAMINER

NICKOL, GARY B

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ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/921,406	Applicant(s) YAKHINI ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Re: Yakhini *et al.*

Date of priority: 08/02/2001

Response to Amendment

The Amendment filed 09-22-2005 in response to the Office Action of 06-17-2005 is acknowledged and has been entered.

Claims 1 and 4 were amended.

Claims 26-33 were added.

Claims 1, 4, and 25-33 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejection Maintained:

Claims 1 and 25 remain rejected and new claims 26-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Bittner *et al.* (Nature, Vol. 406, 3 August 2000, pages 536-560, IDS) for the reasons of record and for the reasons set forth below.

Applicants argue (Response, page 5) that all of the inventors of the present application are listed as authors on Bittner. Applicants further note that because manuscripts are typically submitted to scientific journals well in advance of the publication date, it is intuitive that the subject matter of the claims, to the extent that it might be read on by Bittner, was invented prior to the publication date of Bittner. These arguments have been carefully considered but are not found persuasive. Whether or not all of the inventors of the claimed invention were authors of the cited prior art is not particularly relevant to this line of reasoning as such arguments do not specifically point out any differences between the teachings of the prior art and the claimed subject matter.

It is further noted that applicants have included declarations from seven of the co-inventors pursuant to 37 CFR 1.131 in order to provide evidence of prior invention, including reduction to practice. However, the declarations filed on 09-22-05 under 37 CFR 1.131 are **ineffective** to overcome the Bittner *et al.* reference for the following reason:

The specification teaches (page 21, line 1), “We have proposed that a discrete and previously unrecognizable cancer taxonomy can be identified by viewing the systematized data from gene expression experiments (Bittner et al. Nature 406:536-540, Aug. 3, 2000; incorporated herein by reference). ”

According to the MPEP, where the specification identifies work done by another as “prior art,” the subject matter so identified is treated as admitted prior art. In re Nomiya, 509 F.2d 566, 571, 184 USPQ 607, 611 (CCPA 1975). **MPEP 2129 [R-3]**

Accordingly, the Bittner *et al.* reference is clearly admitted prior art by another. Hence, the declarations submitted under 37 CFR 1.131 are inappropriate. An affidavit or declaration

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under 37 CFR 1.131 is not appropriate where applicant has clearly admitted on the record that subject matter relied on in the reference is prior art. In this case, that subject matter may be used as a basis for rejecting his or her claims and may not be overcome by an affidavit or declaration under 37 CFR 1.131. *In re Hellsund*, 474 F.2d 1307, 177 USPQ 170 (CCPA 1973); *In re Garfinkel*, 437 F.2d 1000, 168 USPQ 659 (CCPA 1971); *In re Blout*, 333 F.2d 928, 142 USPQ 173 (CCPA 1964); *In re Lopresti*, 333 F.2d 932, 142 USPQ 177 (CCPA 1964). **MPEP 715.**

Thus, applicant's arguments and the declarations have not been found persuasive, and the rejection is maintained.

Claims 1, 4, and 25 remain rejected and new claims 26-33 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling for the reasons of record and for the reasons set forth below.

As set forth previously (in part) if the specification discloses that a particular feature or element is critical or essential to the practice of the invention, failure to recite or include that particular feature or element in the claims may provide a basis for a rejection based on the ground that those claims are not supported by an enabling disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

Applicants argue (Response, page 7) that the specification does not recite that comparing increased expression of Wnt5a in a test sample of a tumor compared to the gene expression profile of Wnt5a from a cluster of pair-matched tumor samples is "critical or essential to the

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practice of the claimed methods”. This argument has been carefully considered but is not found persuasive as the rules for this particular rejection under 35 USC 112, 1st paragraph do not appear to require literal support for the words *critical* or *essential*. It is the entire disclosure, which must be considered when determining whether an unclaimed feature is critical or essential. In the instant case, the specification does not clearly teach a method of diagnosing cancer in the absence of critical steps that necessitate the mathematical analysis of gene expression in a series of samples using cluster prediction techniques. (In *Mayhew*, the examiner argued that the only mode of operation of the process disclosed in the specification involved the use of a cooling zone at a particular location in the processing cycle. The claims were rejected because they failed to specify either a cooling step or the location of the step in the process. The court was convinced that the cooling bath and its location were essential, and held that claims which failed to recite the use of a cooling zone, specifically located, were not supported by an enabling disclosure (35 U.S.C. 112, first paragraph)).

Applicants argue that the statistical methods “merely confirm” the results of the claimed methods and that they are not necessary in order to perform the methods. This argument has been carefully considered but is not found persuasive because applicants have not provided any clear rationale or reasoning which supports such a conclusion. As set forth above, it appears that the claimed methods require the mathematical analysis of gene expression in a series of samples using cluster prediction techniques. The title of the disclosure is “Classifying Cancers”, not diagnosing cancers. There is nothing in the disclosure which suggests that the claimed methods can be successfully practiced in the absence of complex cluster prediction modeling. Also, the specification teaches [para 67] that the extent to which melanoma samples can be clinically

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subdivided by expression patterns remains to be *elucidated*. However, our identification of genes **weighted** for their ability to discriminate a subset of melanomas should provide a sound molecular basis for the dissection of other clinically relevant subsets of this tumor. Further, while applicants argue (Response, page 8) that the statistical methods used and described in the specification are not necessary to “understand” the claimed methods, such an argument does not effectively rebut whether or not the statistical methods are critical and or essential for *practicing* the claimed method.

Applicants further argue that the present rejection is similar to that set forth in *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 58 USPQ2d 1891 (Fed. Cir.), *reh ‘g den.*, 59 USPQ2d 1852 (Fed. Cir. 2001). This argument has been carefully considered but is not found persuasive because it would appear that the courts did not rule on this particular issue:

“We are reluctant to decide an issue that the district court has declined to address, at least in a case such as this one in which the resolution of the issue is not plain on its face.”

-*Mycogen Plant Science Inc. v. Monsanto Co.*, 58 USPQ2d 1891 (CA FC 2001)

Thus, applicant’s arguments have not been found persuasive, and the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

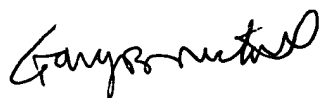
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN



GARY B. NICKOL, PH.D.
PRIMARY EXAMINER